OCT - 4 2001

510(k) Summary

Sponsor Information

Denver Biomedical, Inc.
14998 W. 6th Ave., Bldg. E700
Golden, CO 80401
303-279-7500

Contact Person: Jeff Hill, RA/QA Coordinator

This 510(k) summary was prepared on March 30, 2001.

Device Identification

This special 510(k) is for a modification to the Denver Pleural Effusion Shunt and Pleural Effusion Shunt with External Pump Chamber. The modification is a change in the supplier of the silicone tubing used to fabricate the catheters. The new tubing is very similar to the existing tubing, and the modified devices have been found to be substantially equivalent to the original devices.

Intended Use

The Denver Pleural Effusion Shunt with external pump chamber is used to palliate symptoms of recurrent pleural effusion, an accumulation of fluid in the cavity around the lungs.

Device Description

The Denver Pleural Effusion Shunt with External Pump Chamber has three major components:

1. A 15.5 Fr silicone catheter, which is implanted in the pleural space and collects the accumulated pleural effusion fluid. In the shunt with the externalized pump chamber, the catheter is tunneled subcutaneously and incorporates a polyester cuff.
2. A valved pump chamber, which is either implanted or remains external to the body. The patient compresses the pump chamber to transfer fluid from the pleural space to the peritoneum.
3. A second 15.5 Fr. silicone catheter, similar to the first, which terminates in the abdominal cavity. This catheter also bears a polyester cuff in the shunt with the externalized pump chamber.

Except for the polyester cuff, all components of the shunt are made of silicone rubber.

Summary of the change

The change that was the subject of the special 510(k) was a change in the silicone tubing used to manufacture the catheters. The original silicone tubing is no longer available. The specifications of the originl material have been matched as closely as possible. Testing has verified that the tubing bonds well to the other components of the shunts. Biocompatibility testing has been carried out on the raw elastomer of the silicone tubing and on the finished devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2001

Denver® Biomedical, Inc.
c/o Nancy Sauer, RAC
RDD Consultants, Inc.
401 Spruce Street
LOUISVILLE CO 80027

Re: K012235
Trade/Device Name: Denver® Pleural Effusion Shunt and Denver® Pleural Effusion Shunt with External Pump Chamber
Regulation Number: 21 CFR §876.5955
Regulation Name: Peritoneo-venous shunt
Regulatory Class: II
Product Code: 78 KPM
Dated: September 11, 2001
Received: September 17, 2001

Dear Ms. Sauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012235

Device Name: Denver Pleural Effusion Shunts

Indications For Use:

The Denver Pleural Effusion Shunt is indicated for use in patients with
- chylothorax
- intractable aseptic pleural effusion

The Denver Pleural Effusion Shunt with External Pump Chamber is indicated for adult, pediatric, and neonatal patients with:
- chylothorax
- intractable pleural effusion

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Carolyn J Neuland

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K012235

Prescription Use ✓